

Appendix A. 510(k) Summary of Safety and Effectiveness

NOV 15 1996

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: _____

Applicant Information:

Date Prepared:	April 5, 1996
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Device Information:

Classification	Class II
Trade Name:	Heartport Multifire Clip Applier
Common Name:	Implantable Clip/Vascular Clip/Hemostatic Clip Applier
Classification Name:	Surgical Devices: Implantable Clip, 21 CFR 878.4300 Cardiovascular Prosthetic Devices: Vascular Clip, 21 CFR 870.3250

Equivalent Devices:

The Heartport Multifire Clip Applier is substantially equivalent in intended use and/or method of operation to a combination of the following predicate devices:

1. Pilling Weck - Hemoclip S15 Automatic Applier
2. U.S. Surgical - PREMIUM SURGICLIP Disposable Automatic Clip Applier
3. U.S. Surgical - ENDO CLIP Disposable Appliers
4. Ethicon - LIGACLIP Endoscopic Clip Applier

510(k) Summary of Safety and Effectiveness (continued)**Intended Use**

The Multifire Clip Applier is designed to automatically deliver small hemostatic clips for ligation of blood vessels. The device is intended for use on vessels, which in the opinion of the surgeon, require a small ligating clip. The Multifire Clip Applier may be used during endoscopic procedures such as the endoscopic harvesting of the Internal Mammary Artery.

Comparison To Predicate Devices

The Heartport Multifire Clip Applier is a sterile, single, use disposable device containing 15 small Titanium ligating clips. The device is designed to automatically deliver small hemostatic clips for ligation of blood vessels. The Multifire Clip Applier is equivalent in intended use and operational characteristics to the following devices: (1) Pilling Weck - Hemoclip S15 Automatic Applier, (2) U.S. Surgical - PREMIUM SURGICLIP Disposable Automatic Clip Applier, (3) U.S. Surgical - ENDO CLIP Disposable Appliers and (4) Ethicon - LIGACLIP Endoscopic Clip Applier. All predicates deliver and close a sequence of ligating clips automatically without the need for manual loading of individual clips. The Heartport Multifire Clip Applier combines the same functions as the individual predicate devices into a single clip applier.

Non-Clinical Test Results*Performance:*

The Multifire Clip Applier was evaluated *in vitro* for clip feeding and clip closure functions. In addition, the Clip Applier was evaluated during *in vivo* studies. Performance testing demonstrated that the Heartport Multifire Clip Applier was safe and effective, while meeting the anticipated clinical requirements for its intended use.

Biocompatibility:

The patient contacting materials used in the Multifire Clip Applier are identical to those used in the Pilling Weck - Hemoclip S15 Automatic Applier.

Summary

Based on the product information, intended use, performance and biocompatibility data provided in this Notification, the Heartport Multifire Clip Applier has been shown to be substantially equivalent to currently marketed predicate devices.